

In the United States Court of Federal Claims

**No. 15-1291V
(Filed: July 21, 2021)¹**

KASEY COTTINGHAM,

Petitioner,

v.

**SECRETARY OF HEALTH AND
HUMAN SERVICES,**

Respondent.

**National Childhood Vaccine
Injury Act; 42 U.S.C. § 300aa-
15(e); Attorneys' Fees and Costs;
Reasonable Basis for Claim;
Voluntary Dismissal; Non-
prevailing Petition.**

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and Ann D. Martin, United States Department of Justice, Civil Division, Torts Branch, P.O. Box
146, Benjamin Franklin Station, Washington, D.C. 20044, for Respondent.

OPINION

WILLIAMS, Senior Judge.

This is the fourth opinion by this Court on the issue of whether Petitioner, who voluntarily dismissed her Vaccine Act petition, had a reasonable basis for her claim and is entitled to her attorneys' fees and costs. Because the Special Master erred in requiring Petitioner to adduce medical opinions from treating physicians or experts to establish reasonable basis for the claim, the Court grants Petitioner's motion for review and remands the matter to the Special Master for a reassessment of reasonable basis without requiring a medical or expert opinion supporting causation.

Background

¹ Pursuant to Vaccine Rule 18 of the Rules of the United States Court of Federal Claims, the Court issued its Opinion under seal to provide the parties an opportunity to submit redactions. The parties did not propose any redactions. Accordingly, the Court publishes this Opinion.

On October 30, 2015, Susan Cottingham filed a petition on behalf of her daughter, K.C., seeking compensation for injuries allegedly resulting from K.C.'s receipt of a human-papillomavirus ("HPV") vaccine on July 5, 2012, when she was 14 years old. Specifically, Petitioner claimed that the HPV vaccine caused recurrent headaches, two instances of fainting, and menstrual problems.

Petitioner first contacted counsel on May 15, 2015. Based on his review of the medical records collected as of mid-October 2015, Petitioner's counsel was of the opinion that the onset of K.C.'s vaccine-caused injury occurred on November 1, 2012, and that the applicable statute of limitations would expire on November 1, 2015. Counsel filed the petition on October 30, 2015, but did not yet have all of Petitioner's medical records.

By March 15, 2016, Petitioner's counsel had filed all relevant medical records, and between April and October 2016, contacted two potential experts, but was unable to submit any expert opinion supporting Petitioner's claim. On October 7, 2016, Petitioner filed a motion to dismiss her petition, and the Special Master issued a dismissal decision on October 13, 2016. On October 26, 2016, Petitioner filed a motion seeking attorneys' fees and costs in the amount of \$11,468.77, and the Special Master denied this fee request, finding that Petitioner failed to establish a reasonable basis for her claim.

On April 27, 2017, Petitioner filed her first motion for review. This Court found that the Special Master erred when he relied upon alleged inconsistencies between K.C.'s affidavit and her medical records and failed to consider the impending statute of limitations in assessing reasonable basis. This Court vacated the decision and remanded the matter to the Special Master to "apply a totality of the circumstances standard and reassess whether Petitioner's claim had a reasonable basis at the time the petition was filed and at intervals when additional evidence became available to Petitioner's counsel thereafter." Cottingham v. Sec'y of Health & Human Servs., 134 Fed. Cl. 567, 578 (2017).

On November 7, 2017, while the case was pending before the Special Master on remand, the United States Court of Appeals for the Federal Circuit issued Simmons v. Secretary of Health & Human Services, 875 F.3d 632, 636 (Fed. Cir. 2017), and held that an imminent running of the statute of limitations was not a proper factor to be considered in assessing whether a Vaccine Act claim has a reasonable basis. Despite the Federal Circuit's decision, the Special Master did not follow Simmons and awarded fees in this case, stating that Simmons did not affect his analysis because this "Court's October 12, 2017 Opinion remain[ed] binding." Cottingham on behalf of K.C. v. Sec'y of Health & Human Servs., No. 15-1291V, 2017 WL 6816709, at *6 n.3 (Fed. Cl. Spec. Mstr. Dec. 12, 2017) (citing Strickland v. United States, 423 F.3d 1335, 1338 n.3 (Fed. Cir. 2005)).

On January 10, 2018, Respondent filed a motion for review. In a May 31, 2018 decision, this Court found that Simmons governed this case and remanded this matter to the Special Master to reassess whether Petitioner had a reasonable basis for her claim based on the evidence alone without considering the impending statute of limitations.

On June 20, 2018, the Special Master issued a third decision on the fee petition, finding that there was no reasonable basis for Petitioner's claim because Petitioner provided no evidence that K.C.'s injuries were caused by her vaccination. Cottingham on behalf of K.C. v. Sec'y of

Health & Human Servs., No. 15-1291V, 2018 WL 3432638, at *5 (Fed. Cl. Spec. Mstr. June 20, 2018). On July 19, 2018, Petitioner filed another motion for review arguing that the Special Master erred in his analysis under Simmons and imposed too high of a reasonable basis burden on Petitioner. On November 28, 2018, this Court denied Petitioner's motion for review, and Petitioner subsequently appealed to the Federal Circuit.

On August 19, 2020, the Federal Circuit vacated the Special Master's decision denying attorneys' fees and remanded the matter to the Special Master, finding that the Special Master's determination that Petitioner presented "no evidence" that the vaccine caused K.C.'s injuries was "clearly erroneous because the record does contain objective evidence of causation supporting a reasonable basis." Cottingham on behalf of K.C. v. Sec'y of Health & Human Servs., 971 F.3d 1337, 1346-48 (Fed. Cir. 2020). The appellate court cited the seven medical-examination reports detailing K.C.'s injuries as well as the Gardasil® package insert that identified each of K.C.'s injuries as adverse reactions associated with the Gardasil® vaccine. Id. at 1346.

On remand from the Court of Appeals, the Special Master issued a 68-page decision and again denied attorneys' fees and costs. See Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2021 WL 347020, (Fed. Cl. Spec. Mstr. Jan. 7, 2021), ECF No. 105. In analyzing the Federal Circuit's guidance that "Petitioner must point to evidence of" causation and that "more than a mere scintilla but less than a preponderance of proof could provide sufficient grounds" for a finding of reasonable basis, the Special Master addressed whether objective evidence supported the petition's claim with respect to each of the Althen prongs. ECF No. 105 at 27-28. With respect to Althen's second prong -- "did cause" -- the Special Master found:

[I]f petitioners must present more than a mere scintilla of evidence regarding Althen prong 2, then petitioners must file a statement from a treating doctor or qualified expert indicating that the vaccination harmed the vaccinee because, it would seem, that only treating doctors or qualified experts can express reliable opinions about causation about a particular person. See Vaccine Rule 8(b)(1) (requiring special masters to consider "relevant and reliable evidence"). Of course, people who are not medically trained might offer opinions about causation, but those opinions might not be reliable.

Id. at 28 (emphasis added).

The Special Master analyzed "whether, based on the totality of the circumstances, Ms. Cottingham supported the claims set forth in her petition" -- that the HPV vaccine caused her dysautonomia, headaches, fainting, and menstrual difficulties. Id. at 49-50. The Special Master ruled that Petitioner failed to establish a reasonable basis for the claims in her petition based on the totality of circumstances, emphasizing two points in particular:

The first point is the question of law as to whether an analysis of reasonable basis includes investigating whether a petitioner has presented "objective evidence," concerning the vaccinee's case specifically. As discussed above, this issue arises most prominently in Althen prong 2.

...

The second point underlying the outcome for Ms. Cottingham's motion is evidentiary. Evidence contributing to a finding that Ms. Cottingham did not possess a reasonable basis for the claims set forth in her petition include: (1) the lack of a report from an expert opining that the HPV vaccinations harmed Ms. Cottingham, (2) the lack of a statement from a treating doctor suggesting the HPV vaccinations harmed Ms. Cottingham, (3) the lack of diagnosis to support the assertion of dysautonomia (meaning no unifying syndrome), (4) the presence of alternative causes in the medical records (viral infections for the headaches and dehydration for the fainting), and (5) the long latency between the HPV vaccination and the onset of different problems.

Id. at 62-63 (footnote omitted).

In the event that appellate authorities were to reach different results on either issue, the Special Master went on to determine that the "additional \$15,959.00 in attorney's fees and \$1,106.58 in expenses" requested by Petitioner in her January 4, 2021 supplemental motion for attorneys' fees and costs were reasonable, which would have resulted in a total award of \$114,655.47. Id. at 64, 68. On February 5, 2021, Petitioner filed her third motion for review requesting that this Court "reverse the Special Master's Decision and render a Decision awarding Petitioner \$102,243.20 in attorney's fees and costs." ECF No. 107 at 22.

Discussion

Jurisdiction

This Court exercises jurisdiction pursuant to § 300aa-12(e)(1) of the Vaccine Act. In reviewing a decision rendered by a special master, this Court may: (1) uphold the findings of fact and conclusions of law by sustaining the special master's decision; (2) set aside any findings of fact or conclusions of law "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact or conclusions of law;" or (3) "remand the petition to the special master for further action in accordance with the court's direction." 42 U.S.C. § 300aa-12(e)(2).

A court may conclude that the special master abused his discretion if the special master's decision was "clearly unreasonable, arbitrary, or fanciful," "based on an erroneous conclusion of law," "rests on clearly erroneous fact findings," or, alternatively, that the "record contains no evidence on which the [special master] could rationally base [his] decision." Scanlon v. Sec'y of Health & Human Servs., 116 Fed. Cl. 629, 633 (2014) (quoting Ninestar Tech. Co. v. Int'l Trade Comm'n, 667 F.3d 1373, 1379 (Fed. Cir. 2012)). Where "the special master has 'considered the relevant evidence of record, drawn plausible inferences, [and stated] a rational basis for the decision,' reversible error is extremely difficult to establish." Silva v. Sec'y of Health & Human Servs., 108 Fed. Cl. 401, 405 (2012) (quoting Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)). If the special master's exercise of discretion "turns on the statutory interpretation of the Vaccine Act, a question of law," then the court will review the interpretation "without deference." Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1347 (Fed. Cir. 2008).

Standard for Awarding Attorneys' Fees and Costs

In the landscape of fee-shifting statutes, the Vaccine Act's provision on attorneys' fees is radical in two respects: it prohibits an attorney from charging any fees for services in connection with a petition filed under the Act and authorizes a fee award even when a petitioner does not prevail. The Act expressly states that "[n]o attorney may charge any fee for services in connection with a petition filed under section 300aa-11" of the Vaccine Act, 42 U.S.C. § 300aa-15(e)(3), and provides:

In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover--

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

Id. § 300aa-15(e)(1).

Thus, as the Federal Circuit summarized it, "[w]hen a petitioner is denied compensation for a claim, she may still obtain compensation to cover reasonable attorneys' fees and other costs 'if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.'" James-Cornelius on behalf of E.J. v. Sec'y of Health & Human Servs., 984 F.3d 1374, 1376 (Fed. Cir. 2021) (quoting 42 U.S.C. § 300aa-15(e)(1) and citing Cloer v. Sec'y of Health & Human Servs., 675 F.3d 1358, 1360-61 (Fed. Cir. 2012)).

The Federal Circuit has provided the following guidance on the nature and quantum of evidence necessary to establish reasonable basis:

In Cottingham, we reiterated our prior holding in Simmons that a reasonable basis analysis is limited to objective evidence, and that subjective considerations, such as counsel's subjective views on the adequacy of a complaint, do not factor into a reasonable basis determination. See id. at 1344 (citing Simmons, 875 F.3d at 635). We also explained that the quantum of objective evidence needed to establish reasonable basis for a claim, including causation, is "lower than the preponderant evidence standard required to prove entitlement to compensation," but "more than a mere scintilla." Cottingham, 971 F.3d at 1346.

James-Cornelius, 984 F.3d at 1379.

In Saposnekoo v. Department of Navy, the Federal Circuit noted that "Black's Law Dictionary (4th ed. 1951) defines 'scintilla of evidence' as 'a spark of evidence A metaphorical expression to describe a very insignificant or trifling item or particle of

evidence” 835 F.2d 871, 871 n.2 (Fed. Cir. 1987) (unpublished table decision) (alteration in original). The Federal Circuit in Saposnekoo found that it would be improper to “equate substantial evidence ‘with more than a scintilla of evidence,’” because the standard for substantial evidence “is higher than that minimal one [more than a scintilla]—it must be ‘such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,’ or evidence ‘enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury.’” Id. at 871 (quoting Consolo v. Fed. Mar. Comm’n, 383 U.S. 607, 620 (1966)); see also Arendi S.A.R.L. v. Apple Inc., 832 F.3d 1355, 1360 (Fed. Cir. 2016).

The standard for establishing “more than a mere scintilla of evidence” cannot be met where the evidence is so contrary that a feasible claim is impossible. In Randall v. Secretary of Health & Human Services, No. 18-448V, 2020 WL 7491210, at *12 (Fed. Cl. Spec. Mstr. Nov. 24, 2020), the special master found that there was no reasonable basis for the claim because the petitioner had alleged a SIRVA injury in his left arm, but his medical records indicated that the vaccine was administered in his right arm. The special master in Randall explained: “while petitioner need not show a certain likelihood of success in all [SIRVA] elements, reasonable basis requires that the objective evidence in the record not be so contrary that a feasible claim is not possible.” Id. at *10.

Determining what constitutes “more than a mere scintilla” of evidence is a daunting task. As the Fourth Circuit recently noted:

Standards are easy to recite, but harder to apply. Part of that difficulty, at least for summary judgment standards, lies with confusing terminology like “a scintilla of evidence.” After all, what in the world is a “scintilla?” Given federal courts, as noted above, require more than a scintilla of evidence to avoid summary judgment, understanding what a scintilla is seems necessary to understand if a party has exceeded it. But dating back to the nineteenth century, courts have struggled with the “distinction between what is a scintilla” and what is not. Boing v. Raleigh & G.R. Co., 87 N.C. 360 (N.C. 1882) (remarking that the distinction “is so narrow that it is often very difficult for a court to decide upon which side of the line” evidence falls). . . . Compare Kurtz v. Fels, 63 Wash. 2d 871, 389 P.2d 659, 663 (1964) (holding that proof beyond a mere scintilla requires “facts to be assessed by the senses” and something “tactile” rather than calculations), with Gibson v. Epting, 426 S.C. 346, 827 S.E.2d 178, 181 (2019) (describing scintilla as “a perceptible amount” and “not something conjured up by the shadows”), and Davies v. McDowell Nat. Bank, 407 Pa. 209, 180 A.2d 21, 30 (1962) (dissent) (“‘Scintilla’ means spark.”).

Sedar v. Reston Town Ctr. Prop., LLC, 988 F.3d 756, 761 n.3 (4th Cir. 2021). In Sedar, the Fourth Circuit ruled that summary judgment was not appropriate because the appellant had adduced more than a mere scintilla of evidence, which the Court characterized as “evidence beyond speculation that provides a sufficient basis for a reasonable inference of causation.” Id. at 765 (quoting Penley v. McDowell Cnty. Bd. of Educ., 876 F.3d 646, 655 (4th Cir. 2017)).

In considering potential fee awards to non-prevailing parties, the Federal Circuit has instructed that the Special Master must take into account the Vaccine Act's policy of ensuring that qualified counsel will remain willing to take on these cases. See James-Cornelius, 984 F.3d at 1381. The Federal Circuit explained:

In exercising her discretion, the Special Master must articulate the basis of any discretionary decision to grant or deny fees, keeping in mind the Vaccine Act's remedial objective of maintaining petitioners' access to willing and qualified legal assistance. H.R. REP. 99-908, at 22 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6363 (stating that the Committee "intends that the court make adequate provision for attorneys' time and that the court exercise its discretion to award fees in non-prevailing, good-faith claims").

Id. (emphasis added).

The Special Master Erred in Requiring a Treating Physician's or Expert's Opinion on Causation to Establish a Claim's Reasonable Basis

Petitioner contends that the Special Master erred by holding her to an "elevated standard for establishing reasonable basis that requires an opinion from either a medical expert or a treating physician" that a vaccine caused Petitioner's injury. Petitioner alleges that such a standard is inconsistent with the Federal Circuit's rulings in Cottingham v. Secretary of Health & Human Services, 971 F.3d 1337, 1346 (Fed. Cir. 2020), and James-Cornelius on behalf of E.J. v. Secretary of Health & Human Services, 984 F.3d 1374, 1376 (Fed. Cir. 2021), which "firmly established that neither a treating physician's opinion nor a medical expert opinion is a prerequisite to establishing reasonable basis." ECF No. 107 at 14.

Petitioner is correct, but the Special Master did not have the benefit of the Federal Circuit's guidance in James-Cornelius, decided on January 8, 2021 -- one day after the Special Master's decision now under review.² In James-Cornelius, the Federal Circuit clarified that the "absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has a reasonable basis, especially when the case is in its early stages and counsel may not have had the opportunity to retain qualified experts." 984 F.3d at 1379 (citing Cottingham, 971 F.3d at 1346).

In James-Cornelius, the Federal Circuit found that the petitioner's medical records provided factual support for establishing a claim's reasonable basis, "even in the absence of an express medical opinion on causation." Id. at 1379-80. Similar to the instant case, the records in James-Cornelius showed that the petitioner "experienced a series of symptoms after receiving Gardasil® vaccinations . . . including headache and syncope, adverse reactions recited in the vaccine's package insert." Id. at 1380. There were additional facts supporting causation in James-Cornelius,³ but these do not negate the clear articulation of the legal standard that a medical or expert opinion is not required to establish reasonable basis.

² The Special Master issued his decision under seal on January 7, 2021. ECF No. 104. The motion for review sub judice was filed on February 5, 2021. ECF No. 106.

³ Specifically, the petition in James-Cornelius "alleged that the increase in [the petitioner's] symptoms' severity after his third dose suggested a 'rechallenge,' which has been recognized as a form of causation evidence," documented diagnoses of dysautonomia and POTS, and included

Similarly, although the Federal Circuit in Cottingham ruled that Petitioner “must point to evidence of a causal relationship between the administration of the vaccine and her injuries in order to establish that a reasonable basis for the claim existed when the petition was filed,” the appellate court never suggested that a treating physician’s or expert’s opinion on the ultimate issue was necessary to establish that a claim had a reasonable basis at the time a petition was filed. 971 F.3d at 1346. See also Bekiaris v. Sec’y of Health & Human Servs., 140 Fed. Cl. 109, 115-17 (2018) (stating that “to establish a reasonable basis for a claim, [the] petitioner was obliged to adduce medical evidence going to causation beyond temporal proximity,” but rejecting a requirement for particularized evidence in the form of “an expert report with a specific conclusion to provide a reasonable basis of causation”); McKellar v. Sec’y of Health & Human Servs., 101 Fed. Cl. 297, 303 (2011) (“The presence of a reasonable basis is an objective consideration determined by the totality of the circumstances. Thus, while the initial absence of medical records is one factor a special master may consider in determining whether a claim had a reasonable basis, such absence is not dispositive.” (citation omitted)); see generally Sedar, 988 F.3d at 761, 765 (in assessing whether there was more than “the mere existence of a scintilla of evidence,” examining whether the appellant marshalled “evidence beyond speculation that provides a sufficient basis for a reasonable inference of causation” (citations omitted)).

Nor is the Special Master’s requirement that to establish reasonable basis a petitioner “must file a statement from a treating doctor or qualified expert” indicating causation, consistent with the Vaccine Act. ECF No. 105 at 28. In interpreting the Vaccine Act as imposing this requirement, the Special Master stated:

A focus on treating doctors and qualified experts is not only logical but also consistent with the Vaccine Act. Congress dictated that special masters may find petitioners entitled to compensation only when the claims, as defined in section 11(c)(1)(petitions), were substantiated “by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1). The provision that authorizes attorneys’ fees also depends upon a finding that “there was a reasonable basis for the claim for which the petition was brought.” 42 U.S.C. § 300aa-15(e)(1). Because both section 13(a)(1) and 15(e)(1) reference petitions, a fair understanding of the Vaccine Act as a whole indicates that the analysis of reasonable basis would at least consider whether “medical records” or “medical opinions” support the claims set forth in the petition. See Sebelius v. Cloer, 569 U.S. 369, 377 (2013) (discussing cross-references in section 11(a), and section 15(e)); Heinzelman v. Sec’y of Health & Human Servs., 681 F.3d 1374, 1377 (Fed. Cir. 2012) (construing the Vaccine Act according to the language and design of the statute as a whole).

Id. at 28-29. However, the inclusion of the word “petition” in those two sections is not indicative of the legislative intent the Special Master ascribes here as “petition” ubiquitously appears throughout the Act. Neither the two cited provisions, nor the Vaccine Act as a whole supports the

“three medical journal articles allegedly hypothesizing that these diseases can be caused by the Gardasil® vaccine.” Id. at 1380 (internal citations omitted). Additionally, the record in James-Cornelius included a physician’s note stating ““??VAERS’ in a medical report,” which the special master did not consider in concluding that “[n]one of [the petitioner’s] medical providers associated his symptoms with his vaccinations.” Id. (internal citations omitted).

Special Master's decision requiring a medical opinion as the sine qua non of establishing reasonable basis.

Nor does the Special Master's citation of Sebelius v. Cloer, 569 U.S. 369 (2013), support a conclusion that the Vaccine Act requires a medical opinion to establish reasonable basis. In Cloer, the Court rejected the Government's argument that a petition that does not comply with the Vaccine Act's limitations provision is not a section 300aa-11 petition and thus, is ineligible for fees under 300aa-15(e)(1). Id. at 377. The Court reasoned:

[T]here is no cross-reference to the Act's limitations provision in its fees provision, § 300aa-15(e), or the other section it references, § 300aa-11(a)(1). When these two linked sections are read in tandem they simply indicate that petitions filed with the clerk of the court are eligible for attorney's fees so long as they comply with the other requirements of the Act's fees provision. By its terms, the [Vaccine Act] requires nothing more for the award of attorney's fees.

Id. (emphasis added). Thus, the Supreme Court in Cloer exclusively based the requirement for establishing entitlement to fees on the Vaccine Act's fee provision itself and did not endorse cross-referencing other non-fee provisions to inject elements for establishing causation into the fee analysis.

Finally, a heightened standard of proof -- requiring a medical opinion to establish reasonable basis -- does not comport with "[t]he overarching purpose of the Vaccine Act and the National Childhood Vaccine Injury Compensation Program it created," which "is to award compensation 'to vaccine-injured persons quickly, easily, and with certainty and generosity.'" Cloer, 675 F.3d at 1362 (quoting H.R. Rep. 99-908, at 3), aff'd sub nom. Sebelius v. Cloer, 569 U.S. 369 (2013). As the Supreme Court explained in Cloer, the purpose of the Act's fees provision "was to avoid 'limit[ing] petitioners' ability to obtain qualified assistance' by making awards available for 'non-prevailing, good-faith claims.'" 569 U.S. at 370, 380 (quoting H.R. Rep. No. 99-908, at 22).

In sum, the Special Master erred in requiring that Petitioner provide a medical or expert opinion on causation to show reasonable basis for her claim. Because it is unclear to what extent this legal error affected the Special Master's "totality-of-the circumstances" assessment, this case is remanded to the Special Master.

Remand Order

On remand, the Special Master shall determine whether Petitioner established a reasonable basis for her claim i.e. whether "more than a mere scintilla" of evidence supports Petitioner's claim that the HPV vaccine caused her injuries. In performing this assessment, the Special Master:

- 1) shall evaluate the totality of the circumstances, including:
 - a. The import of James-Cornelius;
 - b. The import of the Gardasil® package insert, considering 21 C.F.R. § 201.57;
 - c. The policies of the Vaccine Act encouraging petitioners to file petitions and obtain qualified counsel to assist them; and

- 2) need not focus exclusively on the Althen factors but may consider other pertinent factors such as the novelty of the vaccine and the claimed injuries.⁴

Conclusion

Petitioner's motion for review is **GRANTED**. The Special Master's decision denying attorneys' fees and costs is **VACATED**, and the case is **REMANDED** to the Special Master for further proceedings consistent with this decision.

s/Mary Ellen Coster Williams

MARY ELLEN COSTER WILLIAMS

Senior Judge

⁴ See Cottingham, 971 F.3d at 1347 (stating that Simmons “did not abrogate a special master’s discretion to analyze novelty”).